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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,825	06/23/2003	Earl Ronald Owen	577122000101	9085

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,825	OWEN ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17,21,24-28 and 30-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17,21,24-28 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 22, 2003 has been considered.

Claim Objections

Claim 21, 24 are objected to because of the following informalities: A claim cannot depend on a cancelled claim. Claim 21 depends from cancelled claim 20 and 24 depends from cancelled claim 23. Both claims 21 and 24 have been read and considered as if dependent solely from claim 13.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 14, 26 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Poppas et al. (1993) Preparation of albumin solder for laser tissue welding in Lasers in surgery and medicine V13:577-580.

Poppas et al., disclose blood (fluid) is composed of mainly protein and that albumin is the principal constituent (see albumin from egg at pages 577 and 588) (as in current claim 26 where the protein is albumin) which is anticipatory of claim 13 since the reference disclosed a sterile solution of albumin (the solution is the same as a suitable solvent). Poppas anticipates egg albumin is 100 to 110% of protein as in claims 14 and 34 (a raw egg cracked open carefully separate the yolk from the albumin (egg white), it is anticipated, absent evidence to the contrary) that the albumin is 100% of the protein relative to water).

Claims 13-17, 25-26 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Poppas et al., Laser Welding in Urethral Surgery: Improved Results with A Protein Solder. J. Urology1988 pages 415-417.

It is anticipated that higher concentrations of claims 13-17, 34-35 of the protein solder (albumin taught on page 416) can be achieved by dissolving the desired concentration of egg albumin (Fisher) in normal saline solution (see bottom half of page 416) absent evidence to the contrary, that 100 mg of egg albumin (Fisher) was dissolved in I ml of normal saline. (Example to achieve a higher concentration 100 mg of egg albumin is dissolved in 100 μl of solvent (water) which is anticipatory of the above claims where the concentration (eg claim 13- 100-120 %) of mass protein relative to water

Claims 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical company Catalog (1993).

Sigma Company Catalog sells Albumin in a solid form (claim 25) (as lyopholized powder page 63, also in a fluid form (claim 26) in a saline solution (suitable solvent) as disclosed by Poppas above.

Claims 15 21, 24 and27 are rejected as been anticipated by Bass et al., US 5,292,362.

Bass et al disclose more than 60% of human albumin is located in the extravascular fluid compartment, absent evidence of the contrary to be 120% mass protein (claim 15). Bass also disclose the protein β-globulins (which contains beta- sheet structure, such as recited in claim 27) at column 5 lines 5.

Column 13, line 46 Bass disclosed the solution (which is a composition) consist of a dye as in claims 21 and 24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-17,21,24-28 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poppas et al., Preparation of albumin solder for laser tissue welding, Lasers in surgery and medicine (1993) V13:577-580 taken with Poppas et al., Laser Welding in Urethral Surgery: Improved Results with A Protein Solder. J. Urology1988 pages 415-417, Sigma Chemical Company Catalog (1993) pages 62-64 and of Bass et al., US 5,292,362.

Poppas et al., teach a sterile albumin solder were the solution is the same as a suitable solvent. Blood is a fluid composed of mainly albumin. Poppas et al., disclosed egg albumin (see pages 577 and 588) as in claims13-14, 26 and 34. Poppas et al. also teaches egg albumin is 100 to 110% of protein as in claims 14 and 34.

Poppas et al. (1988) teach higher concentrations of claims 13-17, 34-35 of the protein solder (albumin taught on page 416) can be achieved by dissolving the desired concentration of egg albumin (Fisher) in normal saline solution (see bottom half of page 416) absent evidence to the contrary, that 100 mg of egg albumin (Fisher) was dissolved in l ml of normal saline. (Example to achieve a higher concentration 100 mg of egg albumin is dissolved in 100 μl of solvent (water) which is anticipatory of the above claims where the concentration (eg claim 13- 100-120 %) of mass protein relative to water

Sigma Company Catalog (1993) sells Albumin in a solid form (claim 25) (as lyopholized powder page 63, also in a fluid form (claim 26) in a saline solution (suitable solvent) as disclosed by Poppas above

Albumin purchased from Sigma can be prepared by dissolving solid albumin (weight by volume of water) in water to the desired concentration as for example discussed in Poppas et al (1993) as an alternative same of albumin.

Sigma (1993) sells lyophilized bovine (a solid protein), and the desired concentration can be obtained by adding an appropriate weight per volume of water. Therefore, Sigma teaches current claims15-17, 25 and 35 of the fluid protein solder to be 100-110, 120-230, 170-230, 210 and 100-120% mass protein relative to water.

Bass teach the protein β-globulins (which contains beta- sheet structure) at column 5 line 5. Bass also teach α- globulins at column 5 line 5. Bass also teach more than 60% of human albumin is located in the extravascular fluid compartment, absent evidence of the contrary to be 120% mass protein (claim 15). Column 13, line 46 Bass disclosed the solution (which is a composition) consist of a dye as in claims 21 and 24.

Although the above references separately do teach the concentration ranges, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the above teachings of Poppas et al (1993and1988), Sigma and Bass to obtain the concentration by dissolving in a fluid (suitable solvent), the albumin bought from Sigma (or as taught by Poppas (fisher) to the desired concentration as recited by applicant in claims 13-17 and 34-35. Thus all the variations (of the fluid protein solder to be 100-110, 120-230, 170-230, 210 and 100-120% mass protein relative to water by using the powdered or solid form of albumin, adjust the weight of the albumin with the

volume of water. (100 ml fluid will require 100 g of albumin to give a 100% mass protein relative to water (or suitable solvent) the concentrations of the claimed invention would have been obtained and obvious to one of ordinary skill in the art of achieving the concentration as claimed by Applicant. It is also obvious to one of ordinary skill in the art to add a dye in the composition as taught by Bass to give strength to the bonding (as the dye will give evidence of bonding strength (see column 15 line 18-30)), also column 6 line 41-48.

Therefore one of ordinary skill in the art would have expected successful results with the use of different concentration, noting that different concentration affects the tensile strength and malleability, since the procedure is to be used for soldering, it is obvious to the ordinary skilled artisan to have the fluid in a sterile condition as taught by Poppas in the material and methods section.

Further one of ordinary skill in the art would have been motivated to combine the teachings of Poppas, Sigma with that of Bass, to obtain a fluid/solid protein solder with concentrations as disclosed by Applicant, with a dye by Bass at the time the claimed invention was made.

Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poppas et al., Preparation of albumin solder for laser tissue welding, Lasers in surgery and medicine (1993) V13:577-580, Poppas et al., Laser Welding in Urethral Surgery: Improved Results with A Protein Solder. J. Urology1988 pages 415-417, Sigma Chemical Company Catalog (1993) and Bass et al., US 5,292,362 as applied to claims13-17, 21, 24-28 and 30-35 above, and further in view of Reich US 4,973,466 where the claims are directed to a strip.

While Poppas et al, (1993 and 1988), Sigma and Bass et al do not teach a kit of claims 30-34 for joining tissues comprising a plurality of strips and/or shapes of the protein solder according to claim 13, the kit according to claim 30 wherein the plurality of strips and/or shapes of the protein solder are sterile, a kit for joining tissues comprising a plurality of strips and/or shapes of the protein solder according to claim 15, the-kit according to claim 32 wherein the plurality of strips and/or shapes of the protein solder are sterile.

Reich teaches (abstract) gels in the form of strips, sheets etc.

The claims differ where Bass did not teach the concentration α- globulins to be less than 10%, nor did Poppas per se teach of the sterility of the protein fluid solder.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the fibronectin and use a protein solder an albumin as taught by Poppas, combine with the teachings Reich to obtain plurality of strips or shapes of protein solder in a kit.

One of ordinary skill in the art would have been motivated to produce plurality of strips of protein solder in a sterile condition for soldering wounds or used in surgery. One of ordinary skill in the art would have been motivated to use albumin instead of fibrinoctin since albumin is also a fragment of blood as taught by Poppas.

Further one skilled in the art would have been motivated to combine the teachings of Poppas, Sigma with that of Bass and Reich as taught since all teachings are for a fluid/solid protein solder.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
7/13/05

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